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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,485	09/18/2000	Ilya Trakht	55099-A-PCT-US/JPW/GJC	4698
7590 05/28/2004				
Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER SCHEINER, LAURIE A	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/664,485

**Applicant(s)**

TRAKHT, ILYA

**Examiner**

Laurie A. Scheiner

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 79-110 is/are pending in the application.
- 4a) Of the above claim(s) 83-88,97,99,100 and 102-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 79-82 and 106-110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/27/01</u> . | 6) <input type="checkbox"/> Other: _____  |

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Applicant's election with traverse of Group I, claims 79-82, 89, 90-96, 98, 101 and 106-110 on November 6, 2003 is acknowledged. Applicants' specie election is also acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the examiner if restriction (and species) were not required.

Applicants' arguments have been considered, however, they have not been found persuasive because a serious search burden does in fact exist. That is, the specifically recited compositions comprising respective monoclonal antibodies must be searched against antibodies found in the commercial data bases, in addition to searches against patented compositions. The number of compositions to which instant compositions are compared have increased substantially in number over time; as time goes forward, individual search results get larger due to literature added to the data bases. Thus, an argument that the search of one composition will necessarily overlap the search of another composition due to functional relatedness does not address the search burden. Moreover, a divergent and non-overlapping search burden is required by the Office because of the structural uniqueness of each composition. A worldwide patent search and a non-patent literature search for relevant terms must be performed. Again, each composition comprises completely different physical properties, such as, primary sequence, and secondary structure. Therefore, each invention is non-obvious over each other. It has been determined that each composition is patentably distinct and a search for more than one of the specific and distinct antibodies and corresponding cancer would pose an undue search burden for the Office.

The requirement is still deemed proper and is therefore made FINAL.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 79-82, 106-110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,197,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibodies of the instant compositions are secreted from the cells (trioma and tetroma) of the patent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 107 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 107 is vague and indefinite since one cannot determine that which is intended by the recitation of "B6B11-like cell" since B6B11 is a specific heteromyeloma cell deposited under accession No. HB-12481.

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The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

It is apparent that the trioma cell ATCC HB 12482 is required to practice the invention as set forth in instant claim 110. Similarly, the heteromyeloma cell ATCC HB 12481 is required to practice the invention as set forth by instant claim 106. Since the respective cells are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed cells are not fully disclosed, nor have they been shown to be publicly known and freely available. The enablement requirements of 35 USC 112 may be satisfied by deposits of the above mentioned cells. The specification does not disclose a repeatable process to obtain the cells. Accordingly, it is deemed that a deposit of these cells should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited two cells under ATCC accession numbers HB 12481 and HB 12482, but there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney or record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that

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the strain will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney or record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Claims 106 and 110 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902.

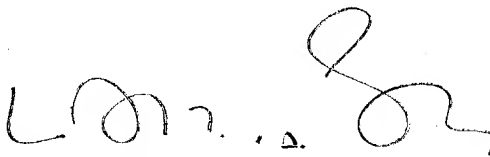
Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

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Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following central fax number: (703) 872-9306.



Laurie Scheiner/LAS  
May 17, 2004



**LAURIE SCHEINER**  
**PRIMARY EXAMINER**